alcohol, wherein the formulation has a pH of about 3.5, a salt concentration of about 20 mM and wherein the polyvinyl alcohol is present at a concentration of about 10%.

26. The method of claim 25 wherein the intranasal formulation is further comprised of citric acid and sodium citrate.

REMARKS

This is in response to the Office Action dated April 9, 2003. Claims 1 – 22 have been rejected under 35 U.S.C. §103(a). Applicants respectfully traverse the rejection. All of the claims have been cancelled and new claims 23 – 26 added to more clearly define the invention.

Rejection under 35 U.S.C. §103 (a)

The claims have been rejected under 35 U.S.C. §103(a) as being unpatentable over Keith (WO 83/00286) in view of Joshi *et al.* (U.S. Patent No. 5,252818) and *Handbook of Pharmaceutical Excipients,* 2nd Ed. Page 383. Applicants respectfully traverse the rejection and request that it be withdrawn for the reasons listed below.

A *Prima facie* Case of Obviousness Has Not Been Established

A *prima facie* case of non-obviousness has not been established because the Joshi reference cannot be combined with the Keith reference because the formulations in the Joshi reference are not directed to intranasal formulations so that one of ordinary skill in the art would not look to Joshi to teach how to make an intranasal formulation of scolpolamine hydrobromide.

Unexpected Superior Properties.

New claims 23 –26 embody the formulation 2 of Example 1. Table one clearly shows that Formulation 2 embodied in claims 23 – 26 produced expectedly higher levels of

scolpolamine being absorbed into the blood stream when administered intranasally as compared to a the prior art composition of Formula 1. See Example 2 pages 15 and 16.

Another unexpectedly superior property of Formulation 2, the claimed invention, is the rapid onset of the drug as is evidenced by the graph which shows scopolamine free base concentrations of Formulation 2 more than doubled that of Formulation 1 in five minutes. See Example 2 page 16. Please note that the data from Example 2 are results from the administration of the scolpolamine hydrobromide to HUMANS. These are human data.

Example 3 shows another unexpectedly superior property of Formulation 2 in that it is far more stable than Formulation 1. The superior property revolves around the fact that the composition of Formulation 1 loses its viscosity very quickly as compared to that of the claimed invention of Formulation 2. The conclusion of the studied stated on line 20 of page 23 stating the following.

"Thus, these data support the surprising conclusion that Formulation 2 containing PVA as a gelling agent is consistently more stable compared to Formulation 1 containing methyl cellulose as a gelling agent over the entire 6 month investigational period at a variety of temperatures and relative humidities."

REQUEST FOR AN INTERVIEW

Applicant's attorney respectfully requests an interview prior to a Final Office action being submitted.

Based upon the amendment and the discussion above, applicants assert that the rejection of the claims under 35 U.S.C. §103(a) has been overcome. Applicants request that the rejection be withdrawn and the claims allowed. Should there remain unresolved issues, it is respectfully requested that the Examiner telephone Paul G. Lunn, Applicants' Attorney at (425) 908-3643 so that such issues may be resolved as expeditiously as possible.

Respectfully Submitted,

OFFICIAL

Paul D Lunn

September 9, 2003
Date

Paul G. Lunn
Attorney/Agent for Applicant(s)
Reg. No. 32743

Paul G. Lunn
Patent Counsel
3450 Monte Villa Parkway
Bothell, WA 98021-8906
Tel. (425) 908-3643

I hereby certify that this correspondence is being transmitted by facsimile to the U.SPTO to the fax number (703) 872-9306 on September 9, 2003:

Sent by facsimile by Leslie Kodish, signature Leslie Kodish.